PTO/SB/01 (03-01) Approved for use through 10/31/2002. OMB 0651-0032

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DECLARATION FOR UTILITY OR **DESIGN** PATENT APPLICATION (37 CFR 1.63)

Declaration Submitted with Initial Filing

Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)

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Attorney Docket Number FSTK 1004-1US		FSTK 1004-1US	
First Named Inventor		MICHAEL G. KAHN	
COMPL	ETE IF	KNOWN	
Application Number	09	974,781	
Filing Date	OC'	TOBER 10, 2001	
Group Art Unit	216	6	
Examiner Name	UNI	KNOWN	

As a below named inventor, I hereby declare that:

My residence, mailing address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

CLINICAL TRIAL PROTOCOL QUALITY USING A MODEL-BASED METHODOLOGY

	(Title of	the Invention)		
the specification of which				
is attached hereto				
OR was filed on (MM/DD/YYYY)	10/10/20	01 as United S	tates Application	Number or PCT International
Application Number 09/97	4,781 and was	amended on (MM/DD/YY	YY)	(if applicable).
I hereby state that I have reviewed amended by any amendment specific	d and understand the co	ontents of the above iden e.	tified specification	n, including the claims, as
I acknowledge the duty to disclose in-part applications, material inform PCT international filing date of the	nation which became av	vailable between the filing	defined in 37 CF g date of the prior	R 1.56, including for continuation- application and the national or
I hereby claim foreign priority ben or plant breeder's rights certificate than the United States of Americ patent, inventor's or plant breeder application on which priority is claim	e(s), or 365(a) of any F a, listed below and ha 's rights certificate(s), o	PCT international applica ve also identified below,	ation which design by checking the	nated at least one country other box, any foreign application for
Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached? YES NO

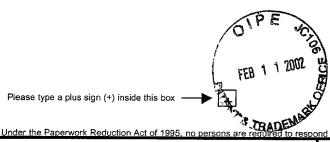
[Page 1 of 2]

Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

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DECLARATION — Utility or Design Patent Application

Direct all correspondence to: IV	stomer Numbe Bar Code Labe	22,7	70	OR Con	orrespondence address below
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I hereby declare that all statements made he are believed to be true; and further that the made are punishable by fine or imprisonmer validity of the application or any patent issued	ese statements ent, or both, un	ts were made with	th the kr	knowledge that willful fa	false statements and the like so
NAME OF SOLE OR FIRST INVEN		_	as be	een filed for this uns	signed inventor
Given Name (first and middle [if any])	CHAEL	G.		ily Name urname	KAHN
Inventor's Signature McCaulo John					Date X 19 Dec 2001
BOULDE	₹R	CC	7	USA	USA
Residence: City	<i>A</i> C	State	´	1 _	
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3980 GREENBR	JAR BO	ULEVAKI)		
Mailing Address				 	
BOULDER	,	CO)	80303	USA
City		State]	1 1	Country
NAME OF SECOND INVENTOR:		A petition has	beer	n filed for this unsig	
Given Name CAROL A	A.		Family	y Name BROVEI	
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Inventor's Signature					Date
MENLO PA	DΚ		\top	TICA	USA
		CA	1	USA	
Residence: City		State	Co	ountry	Citizenship
303 CONCORD Mailing Address	DRIVE	_	_		
MENLO PARK		CA	\Box	94025	USA
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City	1	State	ZIF		Country
Additional inventors are being named on	the 1 supr	plemental Addition	nal Inve	entor(s) sheet(s) PTO/S	SB/02A attached hereto.



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DECLARATION

ADDITIONAL INVENTOR(S) Supplemental Sheet Page _ 1_ of _1_

Name of Additional Joint Inventor, if			☐ A petition has been filed for this unsigned inventor			
Given Name (first and middle [if ar	<u>ny])</u>			Family Na	ame or §	Surname
KELLY A.				K	JNG!	DON
Inventor's Signature						Date
Residence: City SAN RAFAEL	State	CA	Countr	USA		USA Citizenship
4 MOUNT DIABLE Mailing Address	O CIRCI	_E				
Mailing Address	···					
city SAN RAFAEL	State	CA	ZIP	94903	Countr	ry USA
Name of Additional Joint Inventor, if a	iny:		☐ A petif	tion has been file	d for thi	is unsigned inventor
Given Name (first and middle [if an	y])			Family Nan	me or S	Surname
Inventor's Signature						Date
Residence: City	State		Countr	ry		Citizenship
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Name of Additional Joint Inventor, if a			A petitio	n has been filed	for this	unsigned inventor
Given Name (first and middle [if any	1)			Family I	Name o	or Surname
Inventor's Signature						Date
Residence: City	State		Countr	:ry		Citizenship
Mailing Address						***
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DECLARATION FOR UPILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)

Declaration
Submitted
with Initial
Filing

OR

Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)

Attorney Docket Number		FSTK 1004-1US		
First Named Inventor		MICHAEL G. KAHN		
COMPL	ETE IF	KNOWN		
Application Number	09	/ 974,781		
Filing Date	OCTOBER 10, 2001			
Group Art Unit	2160	5		
Examiner Name	UNK	NOWN		

As a below named inventor, I hereby declare that:

My residence, mailing address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

CLINICAL TRIAL PROTOCOL QUALITY USING A MODEL-BASED METHODOLOGY

	(Title of	f the Invention)		
the specification of which		·		
is attached hereto				
OR was filed on (MM/DD/YYYY)	10/10/20	as United S	States Application	Number or PCT International
Application Number 09/97	74,781 and was	amended on (MM/DD/Y)	M)	(if applicable).
I hereby state that I have reviewed amended by any amendment spe	d and understand the co	ontents of the above iden	tified specification	n, including the claims, as
I acknowledge the duty to disclose in-part applications, material inform PCT international filing date of the	maiion which became a	Vallable behveen the tilin	defined in 37 CF g date of the prio	R 1.56, including for continuation- r application and the national or
I hereby claim foreign priority ben or plant breeder's rights certificat than the United States of Americ patent, inventor's or plant breeder application on which priority is claim	e(s), or 365(a) of any f a, listed below and ha r's rights certificate(s) o	PCT international application also identified helow	ation which design	inated at least one country other
Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached? YES NO

Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

[Page 1 of 2]

PTO/SB/01 (03-01)
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DECLARATION — Utility or Design Patent Application

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DECLARATION

ADDITIONAL INVENTOR(S) Supplemental Sheet Page _1 of _1_

Name of Additional Joint Inventor, if any: A petition has been filed for this unsigned inventor						this unsigned inventor	
Given Name (first and middle [if any])				Family Name or Surname			
KELLY A.					KINC	DON	
Inventor's Signature						Date	
Residence: City SAN RAFAEL	s	C.	A	Country	SA	USA Citizenship	
4 MOUNT DIABLO CIRCLE Mailing Address							
Mailing Address							
city SAN RAFAEL	S	tate C	A	zip 94903	Coun	try USA	
Name of Additional Joint Inventor, if	any:		Ε	A petition has been	filed for th	nis unsigned inventor	
Given Name (first and middle [if a	ny])			Family Name or Surname			
Inventor's Signature						Date	
Residence: City	St	ate		Country		Citizenship	
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Name of Additional Joint Inventor, if	any:			A petition has been fi	led for this	s unsigned inventor	
Given Name (first and middle [if any	/])	'	Family Name or Surname				
							
Inventor's Signature						Date	
Residence: City	Stat	e		Country		Citizenship	
Mailing Address							
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Burden Hour Statement: This form is estimated to take 21 minutes to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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DECLARATION FOR UTILITY OR
DESIGN
PATENT APPLICATION
(37 CFR 1.63)

Declaration Submitted with Initial Filing

Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)

Attorney Docket Number		FSTK 1004-1US		
First Named Inventor		MICHAEL G. KAHN		
COMPLETE IF		KNOWN		
Application Number	09	974,781		
Filing Date	OCTOBER 10, 2001			
Group Art Unit	216	5		
Examiner Name	UNK	KNOWN		

As a below named inventor, I hereby declare that:

My residence, mailing address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

USING A MODEL-BASED METHODOLOGY								
L	(Title of	the Invention)						
the specification of which	•							
is attached hereto								
OR ✓ was filed on (MM/DD/YYYY)	10/10/20	as United S	itates Application	Number or PCT International				
Application Number 09/97	74,781 and was a	amended on (MM/DD/YY	m	(if applicab	ole).			
I hereby state that I have reviewed amended by any amendment spe	d and understand the co cifically referred to abov	ontents of the above ident	tified specification	ı, including the claims, as				
I acknowledge the duty to disclose in-part applications, material inforr PCT international filing date of the	mation which became av	vallable between the filing						
I hereby claim foreign priority ben or plant breeder's rights certificate than the United States of Americ patent, inventor's or plant breeder application on which priority is claim	te(s), or 365(a) of any F ca, listed below and hav r's rights certificate(s), o	PCT international applica ve also identified below,	ation which design by checking the	nated at least one country off box, any foreign application	ther for			
Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached	?			
Additional foreign application	numbers are listed on a	supplemental priority dat	ta sheet PTO/SB/	02B attached hereto:				

[Page 1 of 2]

PTO/SB/01 (03-01)

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DECLARATION — Utility or Design Patent Application

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Address						
City			State		ZIP	
Country	Tele	ephone			Fax	
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.					and the like so	
NAME OF SOLE OR FIRST INVENTOR	: [A petition h	as bee	n filed for this ur	signed invent	or
Given Name (first and middle [if any])	AEL	G.	Family or Sur		KAHN	T
Inventor's Signature					Date	
BOULDER BOULDER		CC	- 1	USA		USA
Residence: City State Country Citizenship 3980 GREENBRIAR BOULEVARD						
Mailing Address						
BOULDER		CO State)	80303 zip	Country	USA
NAME OF SECOND INVENTOR:			been f			
iven Name carrolled Family Name corrolled Fa						
inventor's Signature					Date	
MENLO PARK Residence: City		CA State	Cou	USA	Citizenship	USA
303 CONCORD DRIVE						
MENLO PARK		CA State	ZIP	94025	Country	USA
Additional inventors are being named on the 1_supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto.						

FEB 1 1 2002 PTO/SB/02A (11-00)

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ADDITIONAL INVENTOR/S) Please type a plus sign (+) inside this box

DECLARATION

Supplemental Sheet Page _1_ of _1_

ame of Additional Joint Inventor, if any:							
Given Name (first and middle [if any])			Family Name or Surname				
		ľ		K)	[NG]	DON	
Inventor's X Lell a Kingdo					Date 12-13-01 USA		
Residence: City SAN RAFAEL State CA Country			USA		USA Citizenship		
.O C	IRCLE		·				
St	ate C	A	ZIP 94	4903	Countr	y USA	
any:		Е	A petition h	as been filed	l for thi	s unsigned inventor	
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Name of Additional Joint Inventor, if any: A petition has been filed for this unsigned inventor							
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POWER OF ATTORNEY OR AUTHORIZATION OF AGENT

Application Number	09/974,781
Filing Date	October 10, 2001
First Named Inventor	Michael G. Kahn
Title	CLINICAL TRIAL PROTOCOL QUALITY USING A MODEL-BASED METHODOLOGY
Group Art Unit	2166
Examiner Name	Unknown
Attorney Docket Number	FSTK 1004-1US

I hereby appoint:						
✔ Practitioners at	Customer Number 22,47	70	—	lama (Pustu) 'umb er 35 ar	######################################	
OR			L	abel frere	MARK OFFICE	
Practitioner(s) n	amed below:					
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	as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith.					
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Firm or Individual Name	HAYNES BEFFEL & WOLFELD LLP					
Address	P.O. Box 366					
Address						
City	Half Moon Bay	State	CA	Zip	94019	
Country	Unite	d States of	America			
Telephone	(650) 712-0340	Fax	(650) 712-0263			
I am the:						
✓ Applicant/Invent	or.					
	ord of the entire interest. See 37 CF r 37 CFR 3.73(b) is enclosed. (Forn		21			
Statement unde			<u> </u>			
SIGNATURE of Applicant or Assignee of Record						
Name MICHAEL G. KAHN						
Signature Mickel & John						
Date X 19 December 200;						
NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.						
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	Application Number	09/9/4,/81
2002 4	Filing Date	October 10, 2001
FEB 1 TOOL SE	First Named Inventor	Michael G. Kahn
POWER OF ATTORNEY OR	Title	CLINICAL TRIAL PROTOCOL QUALITY USING A MODEL-BASED METHODOLOGY
AUTHORIZA TON OF AGENT	Group Art Unit	2166
	Examiner Name	Unknown
	Attorney Docket Number	FSTK 1004-1US

I hereby appoint:						
✔ Practitioners at C	Customer Number 22,470		→ N	W Bar		
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as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith.						
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Telephone	(650) 712-0340	Fax	(65)	0) 712-02	263	
I am the:		_				
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	ord of the entire interest. See 37 CFR		6)			
Statement unde	Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).					
SIGNATURE of Applicant or Assignee of Record						
Name CAROL A. BROVERMAN						
Signature X ame A. Brown						
Date X January 8, 2002						
NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple						
forms if more than one signature	is required, see below*.					
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POWER OF ATTORNEY OR AUTHORIZATION OF AGENT

Application Number	09/974,781
Filing Date	October 10, 2001
First Named Inventor	Michael G. Kahn
Title	CLINICAL TRIAL PROTOCOL QUALITY USING A MODEL-BASED METHODOLOGY
Group Art Unit	2166
Examiner Name	Unknown
Attorney Docket Number	FSTK 1004-1US

I hereby appoint:					
	Customer Number 22,470				
OR PATENT & TRADEMARK OFFICE					
Practitioner(s) na					
	Name	Registration Number			
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Individual Name					
Address	P.O.	Box 366			
Address	Half Moon Bay State CA Zip 94019				
City Country		tes of America			
Telephone	(650) 712-0340 Fax (650) 712-0263				
I am the:					
Applicant/Invent	or.				
	The state of the s				
Assignee of record of the entire interest. See 37 CFR 3.71.					
Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).					
SIGNATURE of Applicant or Assignee of Record					
Name KELLY A. KINGDON					
Signature X Helly a Kingdon					
Date $X/2-13-\emptyset1$					
NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple					
forms if more than one signature is required, see below*. If the signature is required, see below*. If the signature is required, see below*.					
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09/974,781 **Application Number** October 10, 2001 Filing Date Michael G. Kahn **First Named Inventor** CLINICAL TRIAL PROTOCOL QUALITY USING A MODEL-BASED METHODOLOGY Title 2166 **Group Art Unit** Unknown **Examiner Name** FSTK 1004-1US Attorney Docket Number

I hereby appoint:		THE BALL HALL SHALL SHAL			
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	Assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).				
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SIGNATURE of Applicant or Assignee of Record					
MICHAEL G. KAHN, VICE PRESIDENT					
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Date X 19 December 2001					
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